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TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER
PBD00032/US

C		CERNING A SUBMISSION	ON UNDER 35 U.S.C. 371	WARLES TO BE WAS						
INTE	RNA	TIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED						
		PCT/IB2004/003082	02 September 2004	02 September 2003						
TITLI	OF	INVENTION COMBINATION	ON THERAPY FOR GLYCAEMIC C	CONTROL						
APPL	ICA	NT(S) FOR DO/EO/US PRO	SIDION LIMITED							
Appli	cant	herewith submits to the United States	Designated/Elected Office (DO/EO/US) the f	following items and other information:						
1.	\mathbf{x}	This is a FIRST submission of items	concerning a filing under 35 U.S.C. 371.							
2.		This is a SECOND or SUBSEQUENT submission of items concerning a filing 35 U.S.C. 371								
3.		This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.								
4.	$_$	The US has been elected (PCT Article	e 31).							
5.		A copy of the International Application	on as filed (35 U.S.C. 371 (c)(2))							
	а.	is attached hereto (required only	if not communicated by the International Bur	eau).						
	b.	X has been communicated by the In	nternational Bureau.							
	c.	is not required, as the application	was filed in the United States Receiving Off	ice (RO/US).						
6.		An English language translation of the	e International Application as filed (35 U.S.C	C. 371 (c)(2)).						
	a.	is attached hereto.								
	b.	has been previously submitted un	nder 35 U.S.C. 154(d)(4).							
7.		Amendments to the claims of the Inte	rnational Application under PCT Article 19 ((35 U.S.C. 371 (c)(3))						
	a.	are attached hereto (required only	y if not communicated by the International Bu	ureau).						
	b.	have been communicated by the	International Bureau.							
	c.	have not been made; however, th	e time limit for making such amendments has	s NOT expired.						
	d.	have not been made and will not	be made.							
8.		An English language translation of th	e amendments to the claims under PCT Artic	le 19 (35 U.S.C. 371 (c)(3)).						
9.	X	An oath or declaration of the inventor	r(s) (35 U.S.C. 371 (c)(4)).							
10.		An English language translation of th U.S.C. 371 (c)(5)).	e annexes to the International Preliminary Ex	amination Report under PCT Article 36 (35						
Items	11 1	o 20 below concern document(s) or	information included:							
11.	Щ	An Information Disclosure Statement	under 37 CFR 1.97 and 1.98.							
12.		An assignment document for recording	ng. A separate cover sheet in compliance with	a 37 CFR 3.28 and 3.31 is included.						
13.	X	A preliminary amendment.								
14.		An Application Data Sheet under 37	CFR 1.76.							
15.		A substitute specification.	•							
16.		A power of attorney and/or change of	f address letter.							
17.		A computer-readable form of the sequence	uence listing in accordance with PCT Rule 13	Ster.2 and 37 CFR 1.821 - 1.825.						
18.		A second copy of the published Intern	national Application under 35 U.S.C. 154(d)(4).						
19.		A second copy of the English language	ge translation of the international application	under 35 U.S.C. 154(d)(4).						
20.	Oth	er items or information: International	Published Application, International Search I	Report and International Preliminary Report						

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiatify is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissionor for Potents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO-1390 (Rev. 07-2005)
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111111/16	NO-(if known,	see S7 CFR	(1.5) INTERNATIONA	L APPLICATION		ation unless it displays a valid ATTORNEY'S DOCK	KET NUMBER
<u> </u>			PCI/IB	2004/003082		PBD000	32/US
The following fees are s		/					PTO USE ONLY
I. Basic National Fee	(37 CFR 1.492)	(a))	•••••		\$300	\$ 300.00	
2. Examination Fee (3	7 CFR 1.492(c)		\$ 200.00				
If the written opinion report prepared by IP							
All other situations .		••••••		•••••••••••••••••••••••••••••••••••••••	\$200		
3. Search Fee (37 CFR	1.492(b))				$\neg \uparrow$	\$ 400.00	
			or the International prelimity provisions of PCT Artic				
			on the international applic				
			other than the US and pr				
All other situations	····		TOT	AL OF 21, 22 AN		\$ 900.00	
			l in paper over 100 sheets			900.00	
isting in compliance wi nedium) (37 CFR 1.492	ith 37 CFR 1.82 2(j)).	21(c) or (e)	or computer program listi	ing in an electronic			
Total Sheets	Extra Sheets		Number of each additional 50 or fraction thereof (round up to a	1			
			whole number)				
-100	/50)		x \$250		\$ 0.00	
Surcharge of \$130.00 for the date of comme	or furnishing an	y of the sea national sta	arch fee, examination fee, age (37 CFR 1.492(h))	or the oath or dec	laration	\$ 0.00	
CLAIMS	NUMBER	FILED	NUMBER EXTRA	RATE	1	- <u> </u>	
Total claims	25	- 20 =	5	50.00			
Independent claims	5	1		x 50.00		\$ 250.00	
		-3 =	2	x 200.00		\$ 250.00 \$ 400.00	
MULTIPLE DEPEND	ENT CLAIM(s)		. 1		\longrightarrow		
MULTIPLE DEPEND	ENT CLAIM(s)		. 1	x 200.00 + 360.00		\$ 400.00	
) (if applica	ble)	x 200.00 + 360.00 M CALCULATI	IONS =	\$ 400.00 \$ 360.00	
) (if applica	TOTAL OF CLAI	x 200.00 + 360.00 M CALCULATI	IONS =	\$ 400.00 \$ 360.00 \$ 1010.00	
Applicant claims small	entity status. S	(if applica See 37 CFR	TOTAL OF CLAI	x 200.00 + 360.00 M CALCULATI above are reduced SUBTO	IONS = d by ½.	\$ 400.00 \$ 360.00 \$ 1010.00 \$ 0.00 \$ 1910.00	
Applicant claims small	entity status. S	(if applica See 37 CFR	TOTAL OF CLAI 1.27. The fees indicated ish translation later than 3	x 200.00 + 360.00 M CALCULATI above are reduced SUBTO	IONS = d by ½. DTAL =	\$ 400.00 \$ 360.00 \$ 1010.00 \$ 0.00	
Applicant claims small Processing fee of \$130. earliest claimed priorit	entity status. S .00 for furnishir ty date (37 CFR	See 37 CFR ing the English 1.492(i)).	TOTAL OF CLAI 1.27. The fees indicated ish translation later than 3	x 200.00 + 360.00 M CALCULATI above are reduced SUBTO 0 months from the	IONS = d by ½. OTAL = e	\$ 400.00 \$ 360.00 \$ 1010.00 \$ 0.00	
Applicant claims small Processing fee of \$130. earliest claimed priorit	entity status. S .00 for furnishir ty date (37 CFR	See 37 CFR ing the English 1.492(i)).	TOTAL OF CLAI 1.27. The fees indicated ish translation later than 3 TOT FR 1.21(h)). The Assignm (37 CFR 3.28, 3.31) (\$ 40	x 200.00 + 360.00 M CALCULATI above are reduced SUBTO 0 months from the TAL NATIONAL nent 1.00 per property).	IONS = d by ½. OTAL = e	\$ 400.00 \$ 360.00 \$ 1010.00 \$ 0.00 \$ 1910.00 \$ 1910.00	
Processing fee of \$130. earliest claimed priorit	entity status. S .00 for furnishir ty date (37 CFR	See 37 CFR ing the English 1.492(i)).	TOTAL OF CLAI 1.27. The fees indicated ish translation later than 3 TOT FR 1.21(h)). The Assignm (37 CFR 3.28, 3.31) (\$ 40	x 200.00 + 360.00 M CALCULATI above are reduced SUBTO 0 months from the	IONS = d by ½. OTAL = e	\$ 400.00 \$ 360.00 \$ 1010.00 \$ 0.00 \$ 1910.00 \$ 0.00 \$ 1910.00	
Applicant claims small Processing fee of \$130. earliest claimed priorit	entity status. S .00 for furnishir ty date (37 CFR	See 37 CFR ing the English 1.492(i)).	TOTAL OF CLAI 1.27. The fees indicated ish translation later than 3 TOT FR 1.21(h)). The Assignm (37 CFR 3.28, 3.31) (\$ 40	x 200.00 + 360.00 M CALCULATI above are reduced SUBTO 0 months from the TAL NATIONAL nent 1.00 per property).	IONS = d by ½. OTAL = e	\$ 400.00 \$ 360.00 \$ 1010.00 \$ 0.00 \$ 1910.00 \$ 1910.00	S

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Under the Paperwork Reduction Act of 1965, no persons are required to respond to a collection of information unless it displays a valid OMB control number to cover the above fees is enclosed. A check in the amount of \$ 2006 Please charge my Deposit Account No. 502783 in the amount of \$1910.00 to cover the above fees. A duplicate copy of this sheet is enclosed. The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to my Deposit Account No. 502783. A duplicate copy of this sheet is enclosed. Fees are to be charged to a credit card. Provide credit card information and authorization on PTO-2038. NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status. Send all correspondence to: Mr. Shu M. Lee CUSTOMER NUMBER 38724 Attorney for Applicant Registration No. 41,147 OSI Pharmaceuticals, Inc. 58 South Service Road, Suite 110 Melville, New York 11747 Telephone: (631) 962-2056 Facsimile: (631) 752-3880

10/5/0113

Express Mail No.: ED917409536US Docket No. PBD00032/US

IN THE UNITED STATES PATENT AND TRUE MAR 2006

Applicant(s): PROSIDION LIMITED

International

Application No.: PCT/IB2004/003082

International

Filing Date:

September 02, 2004

Priority Date:

September 02, 2003

For:

COMBINATION THERAPY FOR GLYCAEMIC CONTROL

CERTIFICATE OF MAILING BY "EXPRESS MAIL" UNDER 37 CFR § 1.10

MAIL STOP PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

"Express Mail" mailing number: ED917409536US

Date of Deposit: March 1, 2006

The Following Has Been Deposited:

- Transmittal letter to the united States Designated/Elected Office (DO/EO/US) concerning a filing under 35 USC 371;
- 2) International Published Application WO 2005/020983 A2;
- 3) International Search Report;
- 4) International Preliminary Report;
- 5) Declaration of Inventors;
- 6) Preliminary Amendment; and
- 7) Return Postcard

I hereby certify that all enclosures listed above are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" under 37 CFR § 1.10 on the date indicated below and is addressed to the Assistant Commissioner for Patents, Mail Stop PCT, P.O. Box 1450, Alexandria, VA 22313-1450.

Date of Deposit:

Signature of Person Mailings

Printed Name of Person Mailing:

Respectfully submitted,

Dated: 28 Feb 2006

Mr. Shu M. Lee

Attorney for Applicant

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